GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:3730
ANSWERED ON:13.12.2000
RULES AND REGULATIONS ON MEDICINES AND FIXING PRICES
ANANTRAO GUDHE

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether manufacturing of medicines and fixing of prices is governed by certain set of Government rules and regulations;

(b) if so, the details thereof;

(c) whether any inspection is undertaken before renewing the licences of pharmaceutical companies;

(d) whether the Union Government have any kind of control over these companies; and

(e) if so, the details thereof?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI A. RAJA)

(a) & (b) Yes, Sir. Manufacturing of medicines is regulated under Drugs and Cosmetic Act1940 and the Rules made thereunder. Licences for manufacture of drug under these Rules are issued by the respective Drug Licencing Authorities functioning under State Governments. Prices of drugs are regulated by National Pharmaceutical Pricing Authority (NPPA), Govt. of India under Drug Price Control Order (DPCO).

(c) Inspection of Pharmaceutical Companies are undertaken by the Drug Control Authoritiesunder State Governments before renewing their licences.

(d) to (e) The general control that Government has over companies undertaking manufacturing and marketing activities in other sectors would be applicable in the case of pharmaceutical companies also. However Pharmaceutical Companies are required to obtain necessary permission for manufacture, marketing, import etc. of drugs and formulations, as prescribed under the Drugs and Cosmetics Act, 1940 and rules made thereunder. In so far as pricing aspects are concerned, these are covered by Drugs (Prices Control) Order 1995 issued under the Essential Commodities Act, 1955.